

Naomi A. Igra (SBN 269095)
naomi.igra@sidley.com
SIDLEY AUSTIN LLP
555 California Street
Suite 2000
San Francisco, CA 94104
Telephone: +1 415 772 7495
Facsimile: +1 415 772 7400

Joseph R. Guerra (*pro hac vice* to be submitted)
jguerra@sidley.com
Erika L. Maley (*pro hac vice* to be submitted)
emaley@sidley.com
Sean C. Griffin (*pro hac vice* to be submitted)
sgriffin@sidley.com
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, D.C. 20005
Telephone: +1 202 736 8228
Facsimile: +1 202 736 8711

*Attorneys for Plaintiffs Biotechnology Innovation
Organization and Biocom California*

Beth S. Brinkmann (SBN 129937)
bbrinkmann@cov.com
Mark Mosier (*pro hac vice* to be submitted)
mmosier@cov.com
Conrad Scott (*pro hac vice* to be submitted)
cscott@cov.com
COVINGTON & BURLING LLP
1 CityCenter
850 10th Street N.W.
Washington, D.C. 20001
Telephone: +1 202 662 5312
Facsimile: +1 202 662 6291

*Attorneys for Plaintiff California Life Sciences
Association*

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

BIOTECHNOLOGY INNOVATION
ORGANIZATION; CALIFORNIA LIFE
SCIENCES ASSOCIATION; and BIOCOM
CALIFORNIA,

Plaintiffs,

Civil Case No: 20-cv-08603

**COMPLAINT FOR DECLARATORY
AND INJUNCTIVE RELIEF**

v.

**ADMINISTRATIVE PROCEDURE
ACT CASE**

ALEX M. AZAR, II, in his official capacity as
SECRETARY OF THE UNITED STATES
DEPARTMENT OF HEALTH AND HUMAN
SERVICES; UNITED STATES
DEPARTMENT OF HEALTH AND HUMAN
SERVICES; SEEMA VERMA, in her official
capacity as ADMINISTRATOR OF THE
CENTERS FOR MEDICARE AND MEDICAID
SERVICES; and THE CENTERS FOR
MEDICARE AND MEDICAID SERVICES,

Defendants.

1 Plaintiff Biotechnology Innovation Organization (“BIO”), on behalf of itself and its
 2 members, plaintiff California Life Sciences Association (“CLSA”), on behalf of itself and its
 3 members, and plaintiff Biocom California (“Biocom”), on behalf of itself and its members (together,
 4 “Plaintiffs”), bring suit against Alex M. Azar, in his official capacity as the Secretary of the United
 5 States Department of Health and Human Services (“HHS”); HHS; Seema Verma, in her official
 6 capacity as the Administrator of the Centers for Medicare and Medicaid Services (“CMS”); and
 7 CMS (together, “Defendants”), and allege as follows:

8 INTRODUCTION

9 1. This lawsuit challenges HHS’s issuance, during the final days of the Trump
 10 Administration, of a sweeping new rule that alters the statutorily prescribed method for determining
 11 reimbursement payments that healthcare providers receive for administering “the top 50”
 12 prescription medications to Medicare patients in hospital outpatient departments and other facilities.¹
 13 This eleventh-hour rule was issued in clear violation of the notice-and-comment requirements of the
 14 Administrative Procedure Act (“APA”), and is substantively unlawful and *ultra vires*. The rule is an
 15 impermissible attempt by HHS to use its limited authority to “test” new payment “models” as a basis
 16 for completely rewriting the reimbursement formula Congress enacted.

17 2. Over two years ago, in October 2018, HHS announced that it might revise the
 18 reimbursement formula based on an “international pricing index.” That idea was not set forth in a
 19 proposed rule, but rather in an advanced notice of proposed rulemaking. In November 2020, HHS
 20 issued a new and different reimbursement concept as an immediately effective interim final rule that
 21 will begin altering reimbursement payments as of January 1, 2021—*before the agency even receives*,
 22 much less *considers*, the comments it has solicited on this rule. That action clearly violates the APA.

23 3. HHS has rushed to put its new “Most Favored Nation” Rule (“MFN Rule”) into effect
 24 despite its recognition that there is no “reliable precedent in the U.S. market” for its new
 25 reimbursement formula, and that there is “an unusually high degree of uncertainty” about the

26
 27 ¹ See Final Rule, Most Favored Nation (MFN) Model, 85 Fed. Reg. 76,180 (Nov. 27, 2020) (to be
 28 codified at 42 C.F.R. pt. 513) (“MFN Rule”); Fact Sheet: Most Favored Nation Model for Medicare
 Part B Drugs and Biologicals Interim Final Rule with Comment Period, CMS (Nov. 20, 2020),
<https://tinyurl.com/y65f3qr6>.

1 formula's potential impacts. 85 Fed. Reg. at 76,237. Indeed, HHS acknowledges that, as a result of
 2 the MFN Rule, some healthcare providers may suffer extreme financial hardship, *id.* at 76,222, and
 3 some Medicare patients may receive inferior therapies with “lower efficacy or greater risks,” or end
 4 up “postponing or forgoing treatment” altogether. *Id.* at 76,244. The agency's own estimates show
 5 that, within three years, nearly one in five Medicare Part B patients may have *no* access to drugs
 6 covered by the MFN Rule, *id.* at 76,237–38, and that half of the projected savings to Medicare
 7 “would be due to lost utilization” of these drugs, *id.* at 76,239. In addition, the MFN Rule will
 8 deprive emerging biotechnology companies of their ability to attract crucial financing by seriously
 9 impacting their potential for market-based returns. Such decreases in investment will place critical
 10 research at risk, threatening the ability to develop innovative new drugs, especially for rare diseases.

11 4. HHS's purported justification for giving this unprecedented and harmful rule
 12 immediate effect is that economic disruptions caused by the COVID-19 pandemic have “given rise
 13 to an urgent need for swift action to reduce drug prices,” and that implementation of its new
 14 reimbursement model will provide “immediate relief to Medicare beneficiaries.” *Id.* at 76,249. This
 15 contention is baseless, and cannot justify dispensing with notice and comment on a new policy that
 16 the President has described as “transformative.”² Indeed, the Administration has been pursuing
 17 similar measures for years and never previously asserted that they are a necessary response to the
 18 pandemic. The MFN Rule itself excludes from the new pricing structure all drugs authorized “to
 19 treat patients with suspected or confirmed COVID-19,” 42 C.F.R. § 513.130(b)(ix), on the ground
 20 that applying the MFN Rule to COVID-19 drugs would impair the “rapid, widespread availability of
 21 such drugs in the U.S. to treat patients with suspected or confirmed COVID-19.” 85 Fed. Reg. at
 22 76,191. And this Court recently rejected a similar claim that the economic effects of pandemic
 23 allowed the outgoing Administration to make sweeping policy changes immediately effective
 24 without notice-and-comment. *Chamber of Commerce v. U.S. Dep't of Homeland Sec.*, No. 4:20-cv-
 25 7331, 2020 WL 7043877 (N.D. Cal. Dec. 1, 2020).

26 5. Further, the whole premise of the new Rule is that HHS is *testing* a new

27
 28 ² Remarks by President Trump at Signing of Executive Orders on Lowering Drug Prices, The White House, (July 24, 2020 from 3:45 PM ET to 4:28 PM ET), <https://tinyurl.com/yxhpxvbs>.

1 reimbursement model that it believes will reduce drug prices. HHS cannot claim that it is testing a
2 model to see *if* it reduces drug prices, then declare that the Rule should go into effect immediately
3 because HHS knows that its model *will immediately* reduce drug prices. HHS certainly cannot make
4 such a declaration in light of its admission that its unprecedented model involves “an unusually high
5 degree of uncertainty,” 85 Fed. Reg. at 76,237, and could end up harming—rather than helping—
6 patients, by forcing them to accept riskier or less effective treatments or to forgo treatment during
7 the COVID-19 pandemic. In fact, while HHS claims that implementing the MFN Rule as an interim
8 final rule is necessary to ensure that the pandemic does not cause seniors to “stint[] on care,” *id.* at
9 76,249, it admits that some of the savings it projects are “attributable to beneficiaries *not accessing*
10 *their drugs through the Medicare benefit*,” *id.* at 76,237 (emphasis added).

11 6. Although HHS’s premature conclusions about the outcome of its purported test do not
12 justify its failure to comply with the APA’s notice-and-comment requirements, they confirm the
13 other overarching flaw in its action—namely, that the MFN Rule is not a valid exercise of HHS’s
14 authority to test models. HHS has invoked a provision that allows it to “test” certain payment and
15 patient care “models” on a “defined population,” for which “there are deficits in care leading to poor
16 clinical outcomes or potentially avoidable expenditures.” *See* 42 U.S.C. § 1315a. HHS can expand a
17 test if certain criteria are met, and must report the results of those tests so Congress can consider
18 adopting models into law. *Id.* The MFN Rule plainly falls outside the ambit of this limited authority,
19 and is instead an impermissible attempt to rewrite the “minutely detailed” reimbursement formula
20 Congress enacted for Medicare Part B drugs. *Hays v. Sebelius*, 589 F.3d 1279, 1282 (D.C. Cir. 2009)
21 (citation omitted).

22 7. The reimbursement formula Congress enacted for Medicare Part B drugs is based
23 upon the competitive U.S. market for pharmaceutical products in order to ensure that healthcare
24 providers do not lose money on the drugs that they administer to patients. In general, Medicare Part
25 B covers medical services in the outpatient setting (*e.g.*, visits to a physician’s office or a hospital
26 outpatient facility). Pursuant to that coverage, Part B reimburses providers when they administer
27 drugs to patients during those visits. These provider-administered drugs include many injectable and
28 infusion products that treat serious or life-threatening diseases, like cancer, autoimmune conditions,

1 or end-stage renal disease (“ERSD”). In most cases, the providers must pay out of pocket to
 2 purchase and stock the drugs they administer and may seek reimbursement from Medicare only once
 3 the drug has been administered to a Medicare patient

4 8. Under the existing statute, the government reimburses providers for Part B drugs
 5 under a formula that relies on the “average sales price” (“ASP”) of the drugs in the United States,
 6 plus a small mark-up. 42 U.S.C. § 1395w-3a(b). The MFN Rule disregards that congressional
 7 design. It uses the lowest price charged *outside* of the United States, in one of 22 specified foreign
 8 countries, as the basis for Medicare reimbursements. Far from testing this model on a “defined
 9 population” and in a manner that can later be expanded in a second phase of testing, HHS has made
 10 the reimbursement standard immediately mandatory for the entire country for 50 different drugs
 11 representing approximately 75% of Part B drug spending. 85 Fed. Reg. at 76,193. The Rule was
 12 obviously not designed to test a hypothesis, but instead to alter drug pricing on a wholesale basis.

13 9. The Administration’s own actions and statements prior to issuance of the MFN Rule
 14 confirm this. Legislative proposals to tie Medicare Part B reimbursement rates to foreign drug prices
 15 have been raised since at least 2018, but Congress did not adopt them. Yet, after having failed to
 16 secure passage of such legislation, President Trump issued executive orders in the midst of the
 17 Presidential campaign that purported to “completely restructure the prescription drug market, in
 18 terms of pricing and everything else,”³ by doing what had “never [been] done” before: creating a
 19 “Most Favored Nation” rule for drug pricing.⁴ The President’s September 13, 2020 Order declared
 20 that it was “the policy of the United States” that Medicare not reimburse providers more for Part B
 21 prescription drugs or biological products “than the most-favored-nation price,”⁵ and directed HHS to
 22 implement this policy through rulemaking.

23 10. In accordance with these campaign-inspired directives—not the standards of its
 24 testing authority or any exigencies caused by the COVID-19 pandemic—HHS issued its new MFN
 25 Rule to “completely restructure the prescription drug market.” In doing so, it has exceeded its

26 ³ Remarks by President Trump at Signing of Executive Orders on Lowering Drug Prices, The White
 27 House (July 24, 2020 from 3:45 PM ET to 4:28 PM ET), <https://tinyurl.com/yxhpxvbs>.

28 ⁴ *Id.*

⁵ Executive order on Lowering Drug Prices by Putting America First, The White House (Sept. 13,
 2020), <https://tinyurl.com/yynzmt4>.

1 narrow authority to test limited models.

2 11. The agency's action also runs counter to the Medicare Act's access to therapies
3 provision, 42 U.S.C. § 18114, because implementing foreign price controls in the United States will
4 severely undermine access to medicine in the United States, as well as eviscerate innovation and the
5 development of lifesaving medicines and other biological products.

6 12. HHS's interpretation of the testing provision is so broad and lacking in substantive
7 limitations that, if accepted, it would render that provision—and its authorization to waive aspects of
8 the Social Security Act—unconstitutional under the non-delegation doctrine. It would also violate
9 the Presentment Clause and the constitutional principle of separation of powers.

10 **PARTIES**

11 13. Plaintiff Biotechnology Innovation Organization ("BIO") is a nonprofit corporation
12 organized under the law of Washington, D.C., with its principal place of business in Washington,
13 D.C. BIO is the world's largest biotechnology trade association, representing more than 1,000
14 biotechnology companies, academic institutions, state biotechnology centers and related
15 organizations across the United States and in more than 30 other nations. Hundreds of BIO's
16 members are located in California. BIO members are involved in the research and development of
17 innovative healthcare and biotechnology products, including the first biologic products, the first
18 targeted therapies for oncology, and recombinant DNA products.⁶ As described below, the MFN
19 Rule will be devastating to such biotechnology innovation.

20 14. Plaintiff California Life Sciences Association ("CLSA") is a nonprofit organization
21 organized under California law, with its principal place of business in South San Francisco,
22 California. CLSA is the state's largest life sciences advocacy and business leadership organization,
23 and it works closely with industry, government, academia, patient groups, and others to shape public
24 policy, improve access to innovative technologies and grow California's life sciences
25 economy. CLSA serves biotechnology, pharmaceutical, medical device and diagnostics companies,
26 research universities and institutes, investors and service providers throughout the Golden State.⁷

27 ⁶ A list of BIO members is available at *BIO Member Directory*, <https://tinyurl.com/y4r3y5tj>.

28 ⁷ A list of CLSA members is available at *CLSA Member Directory*, <https://tinyurl.com/yxvxvewc>.

1 Over one thousand of CLSA's member companies are located in California.

2 15. Plaintiff Biocom California ("Biocom") is a nonprofit corporation organized under
3 California law, with its principal place of business in San Diego, California. Biocom is an
4 international life sciences advocacy and business organization representing more than 1,300
5 members—the vast majority of which are located in California—to drive public policy, build a
6 network of industry leaders, create access to capital, introduce cutting-edge workforce development
7 and STEM education programs, and create robust value-driven purchasing programs. Biocom serves
8 life sciences, pharmaceutical, medical device, genomics, and bioinformatics companies.

9 16. The MFN Rule is of vital concern to BIO, CLSA, Biocom and their members and
10 partners. Several of BIO's, CLSA's, and Biocom's members manufacture drugs and biological
11 products subject to the MFN Rule, and they will be directly harmed by the MFN Rule. BIO, CLSA,
12 and Biocom also have members who are academic centers, investors, and research institutes, who
13 will be harmed by the MFN Rule because it will decrease investment in pharmaceutical innovation.
14 This suit seeks to protect interests that are germane to plaintiffs' purposes because the MFN Rule
15 directly impacts the goals of plaintiffs to advocate for public policies that encourage investment in
16 innovative biotechnology products. None of the claims asserted in this complaint nor the relief
17 sought require plaintiffs' members to be parties.

18 17. California is home to more than 3,700 life sciences companies. This innovation
19 ecosystem in California has built companies that produce some of the world's most important and
20 innovative therapies. California's life sciences sector directly employs 323,723 people throughout
21 the state in for-profit companies, universities, and nonprofit research institutes. When indirect and
22 induced employment are factored in, the sector accounts for almost 1 million jobs. The Bay Area led
23 the state with 87,441 direct life sciences jobs. In 2019, California companies entered more than
24 1,380 medicines into clinical trials. Many are intended to treat areas of major unmet medical need,
25 such as cancer, neurodegenerative conditions, and infectious diseases. The MFN Rule directly
26 threatens this critical innovation ecosystem.

27 18. Defendant HHS is responsible for administering, among other things, the Medicare
28 programs and has authority to test payment models under the Patient Protection and Affordable Care

1 Act, Pub. L. No. 111-148, § 3021, 124 Stat. 119, 389 (2010) (the “PPACA”) (codified at 42 U.S.C. §
2 1315a).

3 19. Alex M. Azar is Secretary of HHS (the “Secretary”) and is sued in his official
4 capacity.

5 20. Defendant Seema Verma is the Administrator of CMS, and is sued in her official
6 capacity.

7 21. Defendant CMS is a federal agency within HHS, and the Center for Medicare and
8 Medicaid Innovation (“CMMI”) is a component of CMS that is responsible for administering the
9 PPACA’s provision for testing models. CMS, together with HHS, promulgated the MFN Rule
10 challenged in this lawsuit.

11 JURISDICTION AND VENUE

12 22. Subject matter jurisdiction is founded on 28 U.S.C. § 1331 because this case arises
13 under the Constitution and laws of the United States.

14 23. An actual controversy exists between the parties within the meaning of 28 U.S.C.
15 § 2201, and this Court has the authority to grant declaratory and injunctive relief pursuant to 28
16 U.S.C. §§ 2201 and 2202.

17 24. Venue lies in this district under 28 U.S.C. § 1391(e)(1) because this is a judicial
18 district in which plaintiff CLSA resides, and this action seeks relief against federal agencies and their
19 officials acting in their official capacities.

20 25. The MFN Rule is an interim final rule, which constitutes final agency action. *See*
21 *Career College Ass’n v. Riley*, 74 F.3d 1265 (D.C. Cir. 1996).

22 FACTUAL BACKGROUND

23 *The September 13, 2020 Executive Order*

24 26. The MFN Rule asserts that it is an emergency response to economic disruptions
25 caused by the COVID-19 pandemic, and that it falls within the agency’s statutory authority to test
26 payment models. However, the Administration has been seeking to tie U.S. drug prices to foreign
27 prices one way or another for years—well before the pandemic began—and resorted to its new MFN
28

1 Rule only after it failed to secure passage of legislation.

2 27. President Trump stated in his January 30, 2018 State of the Union Address that he
3 was “direct[ing] [his] administration to make fixing the injustice of high drug prices one of our top
4 priorities,” that “[p]rices would come down” and that “[i]n many other countries, these drugs cost far
5 less than what we pay in the United States.”⁸

6 28. On May 11, 2018, President Trump issued a “Blueprint to Lower Drug Prices,”
7 stating that the United States bears the “burden of financing drug development” because “[o]ther
8 countries use socialized healthcare to command unfairly low prices from U.S. drug makers.”⁹

9 29. The President stated in September 2019 that he wanted Congress to address drug
10 prices: “the American people need Congress to help,” and “[l]et’s get it done in a bipartisan way!”¹⁰

11 30. Secretary Azar declared the COVID-19 pandemic to be a public health emergency on
12 January 31, 2020, with retroactive effect to January 27, 2020. The Secretary’s declaration made no
13 mention of a need to change the way Part B drugs were reimbursed.

14 31. On July 2, 2020, the President expressed his frustration with the failure to pass
15 legislation regarding drug pricing, stating, “We MUST lower drug prices for patients!” and that
16 “@HouseGOP . . . ha[s] SHOWN LEADERSHIP while . . . @SenateDems WALK AWAY!”¹¹ The
17 President did not assert, however, that drug prices must be lowered to fight the COVID pandemic.

18 32. Despite President Trump’s efforts to seek passage of legislation to tie U.S. drug
19 prices to foreign prices, and Congress’ consideration of several bills that would have changed the
20 statutory formula for Medicare drug pricing (including one that would have used international
21 reference pricing benchmarks), Congress did not pass any such bills into law. On July 24, 2020,
22 President Trump attempted to bypass Congress by signing four “sweeping” Executive Orders
23 designed to “significantly lower the cost of prescription drugs while increasing access to life-saving
24

25 ⁸ President Donald J. Trump’s State of the Union Address, The White House (Jan. 30, 2018),
26 <https://tinyurl.com/ybtdytqa> (remarks as prepared for delivery).

27 ⁹ President Donald J. Trump’s Blueprint To Lower Drug Prices, The White House (May 11, 2018),
28 <https://tinyurl.com/y9q5zxjm>.

¹⁰ @realDonaldTrump, TWITTER (Sept. 19, 2019, 5:42 PM), <https://tinyurl.com/y4u29jtr>.

¹¹ @realDonaldTrump, TWITTER (July 2, 2020, 5:45 PM), <https://tinyurl.com/yxgr3oxz>.

1 medications”¹² He described these four orders as “a bold and historic, very dramatic action to
 2 reduce the price of prescription drugs for American patients and American seniors.”¹³ He further
 3 stated that they would be the “most far-reaching prescription drug reforms ever issued by a
 4 President. Nothing even close.”¹⁴ These Executive Orders were announced in a press release
 5 entitled: “Congress Didn’t Act on Prescription Drug Prices. So President Trump Did.”¹⁵

6 33. These orders were designed to “completely restructure the prescription drug market,
 7 in terms of pricing and everything else.”¹⁶ One was designed to “ensure[] the United States pays the
 8 lowest price available among economically advanced countries for Medicare Part B drugs.”¹⁷

9 34. This Executive Order, called “Lowering Drug Prices by Putting America First,” was
 10 described by President Trump at the July 24, 2020 press conference. The President stated that,
 11 pursuant to this Executive Order, the United States “will determine what other medically advanced
 12 nations pay for the most expensive drugs, and instead of paying the highest price, Medicare will pay
 13 the lowest price and so will lots of other U.S. buyers.”¹⁸ He went on to state that “Medicare is the
 14 largest purchaser of drugs anywhere in the world by far. Medicare—largest purchaser of drugs in the
 15 world. And we’re finally going to use that incredible power to achieve a fairer and lower price for
 16 everyone. Everyone will get a fairer and much lower price. This is not talking about one half of a
 17 percent. This is big stuff.”¹⁹ The President did not state, however, that the Executive Order would
 18 alleviate economic hardship caused by the COVID-19 pandemic, which had been ongoing for
 19

20 ¹² Congress Didn’t Act on Prescription Drug Prices. So President Trump Did, The White House
 21 (July 27, 2020), <https://tinyurl.com/y5zye4oe>; President Donald J. Trump Is Taking Action to Lower
 22 Drug Costs and Ensure That Americans Have Access to Life-saving Medications, The White House
 23 (July 24, 2020), <https://tinyurl.com/y5lyzcg7>.

¹³ Remarks by President Trump at Signing of Executive Orders on Lowering Drug Prices, The White
 House (July 24, 2020 from 3:45 PM ET to 4:28 PM ET), <https://tinyurl.com/yxhpxvbs>.

¹⁴ *Id.*

¹⁵ Congress Didn’t Act on Prescription Drug Prices. So President Trump Did, The White House (July
 24 27, 2020), <https://tinyurl.com/y5zye4oe>.

¹⁶ *Id.*

¹⁷ *Id.*; President Donald J. Trump Is Taking Action to Lower Drug Costs and Ensure That Americans
 25 Have Access to Life-saving Medications, The White House (July 24, 2020),
 26 <https://tinyurl.com/y5lyzcg7>.

¹⁸ Remarks by President Trump at Signing of Executive Orders on Lowering Drug Prices, The White
 27 House (July 24, 2020 from 3:45 PM ET to 4:28 PM ET), <https://tinyurl.com/yxhpxvbs>.

¹⁹ *Id.*

1 months by then.

2 35. While President Trump reportedly signed the Executive Order on July 24, 2020, a
3 copy of this Order was not released.

4 36. Instead, President Trump stated this Order would be held “until August 24th, hoping
5 that the pharmaceutical companies will come up with something that will substantially reduce drug
6 prices. And the clock starts right now. So it’s August 24th at 12:00, after which the order on favored
7 nations will go into effect.”²⁰

8 37. The Order was not released on August 24. Instead, on September 13, 2020, President
9 Trump issued a new version of the Lowering Drug Prices by Putting America First Executive Order,
10 which revoked the never-released July 24, 2020 Order of the same name.²¹

11 38. The September 13, 2020 Executive Order states that “Americans pay more per capita
12 for prescription drugs than residents of any other developed country,” and that “[i]t is unacceptable
13 that Americans pay more for the exact same drugs.” *Id.* It further states that “Americans finance
14 much of the biopharmaceutical innovation that the world depends on,” thereby “effectively
15 subsidizing innovation and lower-cost drugs for the rest of the world,” and that the federal
16 government “should insist on, at a minimum, the lowest price at which the manufacturer sells that
17 drug to any other developed nation.” *Id.*

18 39. As to the “policy” it is intended to effect, the Executive Order states “[i]t is the policy
19 of the United States that the Medicare program should not pay more for costly Part B prescription
20 drugs or biological products than the most-favored-nation price,” defined as the price available “in a
21 member country of the Organisation for Economic Co-operation and Development (OECD) that has
22 a comparable per-capita gross domestic product.” *Id.*

23 40. That Executive Order directs the HHS Secretary to “immediately take appropriate
24 steps to implement his rulemaking plan to test a payment model pursuant to which Medicare would
25

26 ²⁰ *Id.*

27 ²¹ Executive Order on Lowering Drug Prices by Putting America First, The White House (Sept. 13,
28 2020), <https://tinyurl.com/yynzmtn4>; *see id.* § 5 (“The Executive Order of July 24, 2020 (Lowering Drug Prices by Putting America First), is revoked.”).

1 pay, for certain high-cost prescription drugs and biological products covered by Medicare Part B, no
2 more than the most-favored-nation price.”²²

3 41. The Executive Order does not refer to the COVID-19 pandemic.

4 42. On September 13, 2020—the day that President Trump released the Executive
5 Order—he tweeted that “prices are coming down FAST!”²³ The President also repeated his earlier
6 sentiments about the breadth and far-reaching impact of this Order, tweeting: “My Most Favored
7 Nation order will ensure that our Country gets the same low price Big Pharma gives to other
8 countries. The days of global freeriding at America’s expense are over[,]”²⁴ which Secretary Alex
9 Azar echoed in his own statements, describing the Order as “historic.”²⁵ However, no regulation or
10 proposed rule was issued at that time.

11 43. The MFN Rule was not issued until more than two months later, on November 20,
12 2020. It was not published as a notice of proposed rulemaking for public comment before going into
13 effect. Instead, it was published in the Federal Register on November 27, 2020, as an interim final
14 rule with immediate effect. 85 Fed. Reg. at 76,180. It has a 60-day comment period, which began on
15 the Rule’s effective date and ends on January 26, 2021. *Id.* Upon the MFN Rule’s release, President
16 Trump characterized it as a “groundbreaking rule[] to very dramatically lower the price of
17 prescription drugs,” further stating that it is an “unprecedented reform” “to end global freeloading,”
18 in which higher American drug prices “effectively subsidiz[e] socialism abroad.”²⁶

19 44. The President’s remarks further suggested that the impetus for the release of the MFN
20 Rule was the results of the November 2020 presidential election, asserting that pharmaceutical
21 companies had run “negative advertisements against me during the campaign—which I won, by the
22 way,” and had “even decided not to assess the results of their vaccine; in other words, not come out

23 _____
²² *Id.* § 3.

24 ²³ @realDonaldTrump, TWITTER (Sept. 13, 2020, 2:58 PM), <https://tinyurl.com/yy4nea22>.

25 ²⁴ *Id.*

26 ²⁵ @SecAzar, TWITTER (Sept. 13, 2020, 6:51 PM), <https://tinyurl.com/y4sgktsr> (“President Trump is continuing his historic work to lower drug prices and put American patients first. Today he is moving forward with an executive order to stop foreign free riding and ensure American patients get the discounts given to other countries.”).

27 ²⁶ Remarks by President Trump on Delivering Lower Prescription Drug Prices for All Americans,
28 The White House, (Nov. 20, 2020), <https://tinyurl.com/y6r4g62r>.

1 with a vaccine until just after the election.”²⁷ Indeed, press reports indicate that the MFN Rule was
 2 released in retaliation for the vaccine makers’ alleged “failure” to announce the effectiveness of their
 3 products before the election.²⁸

4 45. The statements by the President and Secretary Azar did not assert that the MFN Rule
 5 was being given immediate effect in order to alleviate any economic hardships caused by COVID-
 6 19.

7 46. As described below, the MFN Rule exceeds HHS’ statutory and constitutional
 8 authority, and violates the notice-and-comment requirements of the APA and the Medicare Act. It
 9 will also cause serious harm to access to medicine and innovation in biotechnology, including to the
 10 members of BIO, CLSA, and Biocom.

11 ***Statutory Requirements for Medicare Part B Coverage and Reimbursement of Certain***
 12 ***Prescription Drugs***

13 47. Medicare is a four-part program that provides health insurance to seniors and persons
 14 with disabilities. “Medicare Part A provides coverage for inpatient care, i.e., care provided while a
 15 patient is admitted to a hospital or skilled nursing facility. Medicare Part B covers various other
 16 services including outpatient (or same-day) hospital care.” *See generally Am. Hosp. Ass’n v. Azar*,
 17 967 F.3d 818, 820 (D.C. Cir. 2020). Part C relates to certain health insurance programs run by
 18 Medicare Advantage Companies, and Part D covers certain prescription drugs, including vaccines.
 19 *See generally* What’s Medicare?, Medicare.gov, <https://tinyurl.com/yajxwvdz>.

20 48. Among other things, Medicare Part B covers drugs that are administered in doctor’s
 21 offices, hospital outpatient clinics, or similar facilities, as well as some oral oncology medicines. *See*
 22 42 U.S.C. §§ 1395k(a)(2)(B), 1395x(s)(20)(A)–(B). The same drugs are also administered to patients

23 _____
 24 ²⁷ *Id.*

25 ²⁸ *See* Paige Cunningham, The Health 202: Trump is angry at vaccine makers, so he’s pushing a last-
 26 minute plan to lower drug prices, Washington Post (Nov. 17, 2020), <https://tinyurl.com/yxh6swmf>
 27 (“President Trump is infuriated that Pfizer and Moderna announced their coronavirus vaccines are
 28 highly effective after Joe Biden was declared the victor in the presidential election – a move Pfizer’s
 CEO insisted wasn’t politically motivated. Now the president is trying to get back at the
 pharmaceutical industry in the waning weeks of his administration” by issuing the MFN Rule);
 @realDonaldTrump, TWITTER, (November 9, 2020, 7:43 PM), <https://tinyurl.com/y4j68elg> (“[T]he
 Democrats didn’t want to have me get a Vaccine WIN, prior to the election, so instead it came out
 five days later – As I’ve said all along!”).

1 who are not Medicare enrollees (for example, patients with private insurance).

2 49. In crafting Medicare Part B, Congress struck a careful balance between preserving the
3 innovation and dynamism of a free market, and ensuring beneficiaries' access to affordable
4 treatment.

5 50. Reimbursement rates—the prices Medicare pays to doctors to reimburse them for
6 dispensing covered drugs to Medicare patients—are a key determinant of that balance. Because
7 Medicare Part B patients pay for a portion of their own treatment in the form of cost-sharing,
8 reimbursement rates directly affect their cost of care. But reimbursement rates that are too low
9 render treatment inaccessible, because healthcare providers do not have the financial ability to
10 purchase drugs at a higher price than the price for which Medicare will reimburse them. *See* ¶¶ 86,
11 98, 117, *infra*.

12 51. Hence, Congress chose to tie the Part B reimbursement rates to the market price for
13 the covered drug in the United States—in Medicare parlance, its ASP. Because market prices
14 include—by definition—an adequate return on investment to manufacturers, tying the Part B
15 reimbursement rate to ASP also helps ensure innovation in new drugs and biologics. The
16 relationship between market prices and Medicare prices is so important that Congress has
17 specifically fixed it by statute.

18 52. The ASP for a drug or biological generally reflects the manufacturer's sales of the
19 product to specified categories of purchasers in the United States, net of certain discounts, rebates,
20 and other price concessions. 42 U.S.C. § 1395w-3a(b)(4), (b)(6); 42 C.F.R. § 414.804(a).

21 53. Manufacturers report ASPs for their drugs and biologics to CMS by National Drug
22 Code ("NDC"), 42 C.F.R. § 414.804(a)(1).

23 54. ASP reimbursement for Part B drugs and biologics is based on standardized billing
24 and payment codes established under the Healthcare Common Procedure Coding System
25 ("HCPCS") assigned to a particular drug or biological or, in the case of multiple source drugs, a
26 group of drugs assigned to the same HCPCS code. *See* 42 C.F.R. § 414.904(b)(1).

27 55. By law, Medicare's base reimbursement rate for most Part B drugs and biologics is
28 set at 106% of the ASP for each HCPCS code. 42 U.S.C. § 1395w-3a(b)(1), (b)(8).

56. Consistent with the statute, regulations promulgated by CMS set reimbursement for most Part B covered drugs and biologicals at the product's ASP plus 6 percent. *See* 42 C.F.R. § 414.904. This percentage-based markup helps ensure that the Medicare reimbursement rate covers the provider's costs of acquiring and administering these drugs and biologicals.

57. Variations from that base rate have, until the MFN Rule, likewise been set by statute. *See, e.g.*, 42 U.S.C. § 1395w-3a(c)(4) (providing for reimbursement to providers based on the wholesale acquisition cost of a drug or biological during an initial period in which data on sales prices are not sufficiently available to compute an ASP for the drug or biological); 42 U.S.C. § 1395u(o)(1)(A), (D), (E) (providing for reimbursement based on 95 percent of the average wholesale price for vaccines, certain infusion drugs or biologicals furnished through an item of durable medical equipment, and blood and blood products).

58. At present, the Budget Control Act of 2011 ("BCA") requires the annual sequester of nonexempt mandatory federal spending programs, including Medicare. Pursuant to this sequestration requirement, Medicare benefit payments are subject to a 2 percent annual reduction. *See* Budget Control Act of 2011, Pub. L. No. 112-25, § 365, 125 Stat. 240, 256 (2011); *see also* Coronavirus Aid, Relief, and Economic Sec. Act, Pub. L. No. 116-136, § 3709, 134 Stat 281, 421 (2020) (extending Medicare payment reductions through fiscal year 2030).

59. Pursuant to that statutory sequestration requirement, reimbursement for most Part B covered drugs and biologicals is currently reduced from the baseline reimbursement formula of ASP plus 6 percent to ASP plus 4.3 percent. *See, e.g.*, Medicare Payment Advisory Comm'n, *Report to the Congress: Medicare and the Health Care Delivery Sys.* at 80 n.27 (June 2015), <https://tinyurl.com/y4ltu5r4>.

60. No provision of the statute creates a "most-favored-nation" price for Medicare drug reimbursement.

HHS' Limited Statutory Authority to Test Innovative Payment and Service Delivery Models Through the Center for Medicare and Medicaid Innovation

61. HHS issued the MFN Rule pursuant to a provision of the Affordable Care Act that established CMMI within CMS. *See* Patient Protection and Affordable Care Act, Pub. L. No. 111-

1 148, § 3021, 124 Stat. 119, 389 (2010) (codified at 42 U.S.C. § 1315a). The purpose of CMMI is to
 2 “test innovative payment and service delivery models to reduce program expenditures under
 3 [Medicare and/or Medicaid] while preserving or enhancing the quality of care furnished to
 4 individuals under such subchapters.” 42 U.S.C. § 1315a(a)(1).²⁹

5 62. Under this provision, HHS has limited authority to waive or amend certain Medicare
 6 provisions “solely” for purpose of running “tests” on “payment and service delivery models.” 42
 7 U.S.C. § 1315a(b)(1). The results of Phase I tests must be evaluated and, if certain requirements are
 8 satisfied, the duration and scope of such “tests” can be expanded to Phase II through rulemaking. *Id.*
 9 § 1315a(b)(4)(A), § 1315a(c). Only Phase II tests may be conducted on a nationwide basis, and only
 10 after appropriate rulemaking. *Id.* § 1315a(c). The results of such tests must next be reported to
 11 Congress, which can then consider the Secretary’s recommendations to enact any successful models
 12 into law. *Id.* § 1315a(g).

13 63. Not every change to Medicare is a “model” under the statute. In particular, a model
 14 may be tested only if “there is evidence that [it] *addresses a defined population* for which there are
 15 deficits in care.” *Id.* § 1315a(b)(2)(A) (emphasis added). Further, HHS is required to “focus on
 16 models expected to reduce program costs under the applicable subchapter while *preserving or*
 17 *enhancing the quality of care* received by individuals receiving benefits under such subchapter.” *Id.*
 18 (emphasis added).

19 64. The statute sets forth 27 examples of “models”—not one of which addresses the
 20 pricing of, or reimbursement for, prescription drugs. *See id.* § 1315a(b)(2)(B).

21 65. In addition, models may only be tested (and potentially adopted more broadly)
 22 according to a two-step statutory procedure.

23 66. “Phase I” is the “testing” phase. *See id.* § 1315a(b). During testing, the Secretary must
 24 “conduct an evaluation of each model tested” that includes an analysis of “the quality of care

25 ²⁹ The Administration contends that Affordable Care Act is unconstitutional and that none of its
 26 provisions are severable. In a suit currently pending before the United States Supreme Court, the
 27 Administration is asking the Court to strike down the statute in its entirety. *See California v. Texas*,
 28 No. 19-840; *Texas v. California*, No. 19-1019 (argued Nov. 10, 2020). Nonetheless, HHS asserts that
 the MFN Rule is an exercise of CMMI’s authority granted by the Affordable Care Act. *See* MFN
 Rule 42 C.F.R. § 513.1(a), 85 Fed. Reg. at 76,180.

1 furnished under the model, including the measurement of patient-level outcomes and patient-
 2 centeredness criteria determined appropriate by the Secretary; and . . . changes in spending under the
 3 applicable subchapters by reason of the model.” *Id.* § 1315a(b)(4).

4 67. Only upon completing Phase I testing, and “[t]aking into account the evaluation”
 5 described above, may the Secretary in “Phase II” “expand” a model’s “duration” and “scope”—
 6 including by “implement[ing] [it] on a nationwide basis” through “rulemaking.” *Id.* § 1315a(c).

7 68. Before expanding any model, the Secretary must determine that such expansion is
 8 expected to “reduce spending . . . without reducing the quality of care,” or “improve the quality of
 9 patient care without increasing spending.” *Id.* The Secretary must also determine that the expansion
 10 “would not deny or limit the coverage or provision of benefits . . . for applicable individuals” and, in
 11 identifying models to expand, “shall focus on models . . . that improve the quality of patient care and
 12 reduce spending.” *Id.*

13 69. At least once a year, the Secretary is required to report to Congress on Phase I testing,
 14 and this report must “includ[e] the number of individuals . . . participating in [the Phase I] models,”
 15 as well as a list of models chosen for expansion under Phase II. *Id.* § 1315(g). “[E]ach such report
 16 shall provide such recommendations as the Secretary determines are appropriate for legislative
 17 action to facilitate the development and expansion of successful payment models.” *Id.*

18 70. In addition, 42 U.S.C. § 18114 provides that, “[n]otwithstanding any other provision
 19 of this Act, the Secretary of Health and Human Services shall not promulgate any regulation that,”
 20 among other things, “creates any unreasonable barriers to the ability of individuals to obtain
 21 appropriate medical care;” “impedes timely access to health care services;” or “limits the availability
 22 of health care treatment for the full duration of a patient’s medical needs.” CMMI has no authority to
 23 waive this “Access to Therapy” provision.

24 71. 42 U.S.C. § 1315a(d)(2) provides that “there shall be no administrative or judicial
 25 review . . . of six specified aspects of testing models:

26 (A) the selection of models for testing or expansion under this section; (B) the selection
 27 of organizations, sites, or participants to test those models selected; (C) the elements,
 28 parameters, scope, and duration of such models for testing or dissemination; (D)
 determinations regarding budget neutrality under subsection (b)(3); (E) the termination

1 or modification of the design and implementation of a model under subsection
 2 (b)(3)(B); and (F) determinations about expansion of the duration and scope of a model
 3 under subsection (c), including the determination that a model is not expected to meet
 criteria described in paragraph (1) or (2) of such subsection.

4 42 U.S.C. § 1315a(d)(2)(A)–(F). The statute does not otherwise bar judicial review of HHS actions
 5 purportedly taken under § 1315a, including claims that HHS actions are *ultra vires*, unconstitutional,
 6 or failed to adhere to notice-and-comment requirements, such as the challenges at issue here.

7 ***The Most-Favored Nation Rule Is Not An Authorized Test***

8 72. On November 27, 2020, CMS and HHS promulgated the MFN Rule as an interim
 9 final rule with immediate effect.

10 73. The MFN Rule purports to “test” a “payment model” under section 1115A of the
 11 Social Security Act, 42 U.S.C. § 1315a.

12 74. The true purpose of the Rule, however, is clear on its face: to implement President
 13 Trump’s policy—which Congress refused to enact—tying the Medicare reimbursement rates for Part
 14 B drugs or biologicals to “the most-favored-nation price.” Exec. Order No. 13,948, 85 Fed. Reg.
 15 59,649, at § 2(a) (Sept. 13, 2020); *see* 85 Fed. Reg. at 76,182 (“*In response to the September 13,*
 16 *2020 Executive Order, we will implement the MFN Model described in this” rule (emphasis added)).*

17 75. The substance of the MFN Rule likewise demonstrates that it is not a “test” within
 18 CMS’ limited testing authority. The Rule applies nationwide for seven years, and includes no control
 19 group. It is mandatory for all providers who bill Medicare for separately payable Part B medicines,
 20 with limited exceptions. And the products it covers account for approximately 75 percent of Part B’s
 21 expenditures on separately payable drugs and biologicals. 85 Fed. Reg. at 76,193. The point of the
 22 MFN Rule, in other words, is to implement a wholly new policy nationwide, across nearly all of
 23 Medicare Part B and in contradiction of the statutory framework for Medicare Part B—not to “test
 24 [an] innovative payment and service delivery model[.]”

25 76. Providers who dispense drugs subject to the MFN Rule are not reimbursed based on
 26 the mandatory statutory rate set by Congress of ASP plus 6 percent. Instead, the Rule states that
 27 providers will receive an “MFN Drug Payment Amount” plus a flat “Alternative Add-On Payment.”
 28 42 C.F.R. § 513.210(a).

77. The MFN Drug Payment Amount—which the MFN imposes to replace the statutory provision requiring reliance on ASP—is based on the “MFN Price.” The MFN Price is to be derived quarterly, for each individual drug “from the lowest GDP-adjusted country level price” prevailing among the specified countries. *See* 85 Fed. Reg. at 76,196; 42 C.F.R. §§ 513.140(b)(1), 513.210.

78. Subject to certain limitations, the MFN Drug Payment Amount will be 75% ASP and 25% MFN Price in the first year, 50% ASP and 50% MFN Price in the second year, 25% ASP and 75% MFN Price in the third year, and 100% MFN Price in all subsequent years. 42 C.F.R. § 513.210(b)(8).

79. The Alternative Add-On Payment—which replaces the statutory 6 percent of ASP required by Congress—is a flat payment per dose, calculated as 6.1224 percent of a volume-weighted average of historical ASPs for the group of 50 drugs initially subject to the MFN Rule. *See* 42 C.F.R. § 513.220.

80. Far from establishing a limited “test” of this payment model, the MFN Rule provides that it will apply in “all states and U.S. territories.” 42 C.F.R. § 513.220. The Rule likewise applies to all Part B patients who have Medicare as their primary payer and are not covered by other group health plans, 42 C.F.R. §§ 513.2 (defining “MFN Beneficiary”), 513.210(a) (providing that the Rule determines “[t]he total allowed payment amount for an MFN Model drug furnished to an MFN beneficiary by an MFN participant”). Participation in the purported “model” is also mandatory for all Part B health care providers, with few exceptions, *see* 42 C.F.R. §§ 513.100(b) (providing as default that “the MFN Model requires participation by each Medicare participating provider . . . that submits a claim” covered by the Rule); 513.100(c) (excluding only certain specialized providers and certain providers in underserved areas).

81. Moreover, the MFN Rule applies (with certain exclusions, *see* 42 C.F.R. § 513.130(b)) to the “top” Part B drugs, starting with the 50 for which Medicare paid the most money in 2019.³⁰ Drugs that enter the top 50 and do not fall within an exclusion will be added to the list on a yearly basis. 42 C.F.R. § 513.130(a)(2). Drugs are removed from the list, however, only if

³⁰ Fact Sheet: Most Favored Nation Model for Medicare Part B Drugs and Biologicals Interim Final Rule with Comment Period, <https://tinyurl.com/y65f3qr6>; *see also* 42 C.F.R. § 513.130(a)(1).

they are removed from the market (or otherwise terminated from CMS’s coding system) altogether. 42 C.F.R. § 513.130(a)(3). Thus, over time, even more drugs will be subject to the Rule, expanding the program even further beyond what a true “model” might be.

82. The 50 drugs initially included under the MFN Rule “accounted for approximately 75 percent of annual Medicare Part B drug allowed charges for separately payable drugs [in] 2019.” 85 Fed. Reg. at 76,193. HHS projects that in each year the Rule is effective, it will cover drugs that “account for roughly 73 percent of Medicare Part B drug spending.” *Id.* at 76,238. And the MFN Rule is scheduled to be in effect for seven years. 42 C.F.R. § 513.1(c).

83. In short, the MFN Rule is far from being a limited “test” designed to provide information to Congress to consider whether a legislative change is warranted, *see supra* ¶ 61. Rather, it is a sweeping national change to Medicare drug pricing policy imposed by the Administration rather than adopted by Congress.

The MFN Rule Will Have Significantly Adverse Impacts on Patients and Providers

84. HHS acknowledged that there is no “reliable precedent in the U.S. market” for its model, 85 Fed. Reg. at 76,237, and that it lacked “direct experience with policies such as the MFN Model,” *id.* at 76,240.

85. As a consequence, HHS repeatedly acknowledged that there is “an unusually high degree of uncertainty” about the model’s potential impacts. 85 Fed. Reg. at 76,237; *see also id.* at 76,181, 76,230, 76,238, 76,240, 76,243–44, 76,246. Given that uncertainty, HHS candidly acknowledged that the MFN Rule might adversely affect health care providers and Medicare Part B beneficiaries, and that it was “unable to quantify these potential effects of the MFN Model.” *Id.* at 76,244.

86. These adverse impacts are significant. As a result of the MFN Rule, some healthcare providers may suffer extreme financial hardship, *id.* at 76,222, or even go out of business. To avoid such harms, providers may decide not to treat their patients with drugs covered by the MFN Rule and prescribe alternative therapies instead. *Id.* at 76,243–34. In turn, Medicare beneficiaries may suffer “access to care impacts by having to find alternative care providers locally, having to travel to

1 seek care from an excluded provider, receiving an alternative therapy that may have lower efficacy
 2 or greater risks, or postponing or forgoing treatment” altogether. *Id.* at 76,244. HHS further admits
 3 that there is “significant uncertainty with these potential effects,” *id.*, and one study it relies on
 4 estimates that, within three years, nearly one in five Medicare patients will have *no* access to drugs
 5 covered by the MFN Rule. *Id.* at 76,237–38.

6 ***The MFN Rule Was Issued Without Notice or an Opportunity to Comment***

7 87. Despite all of the foregoing uncertainties and potential harms, HHS issued the MFN
 8 Rule without prior notice or opportunity for affected parties to comment. Instead, although HHS
 9 provided a 60-day period for stakeholders to comment on the MFN Rule, it designated the MFN
 10 Rule as an “interim final rule” that is effective immediately and will start altering reimbursement
 11 rates on January 1, 2021—*before* the agency will even receive, much less have an opportunity to
 12 consider, the comments it has requested. That action clearly violates the APA and the Medicare Act.

13 88. Over two years ago, HHS issued an Advance Notice of Proposed Rulemaking in 2018
 14 (“2018 ANPRM”) that discussed an “international price index” model (“IPI Model”). *See* Medicare
 15 Program; Int’l Pricing Index Model for Medicare Part B Drugs, 83 Fed. Reg. 54,546 (Oct. 30, 2018).

16 89. HHS made clear that this “advance” notice was part of its “ongoing work” to develop
 17 the IPI Model, which was merely a “potential model” at the “concept design” stage. *Id.* at 54,547–
 18 50. Indeed, HHS noted that the 2018 ANPRM was intended as a “general solicitation of comments
 19 on several options” and thus “not subject to OMB review.” *Id.* at 54,561. The Advance Notice
 20 further stated that additional comments on the model design would be invited “through notice and
 21 comment rulemaking,” *id.* at 54,550, at which time interested parties would also have an opportunity
 22 to comment on any information collection requirements “through subsequent proposed and final
 23 rulemaking documents.” *Id.* at 54,561.

24 90. The 2018 ANPRM outlined a plan to potentially test a single IPI Model with three
 25 components.

26 91. First, HHS would “contract[] with a number of private-sector vendors that would
 27 supply [providers] with the drugs and biologicals that [HHS] would include in the [IPI Model] in all
 28

of the model’s selected geographic areas.” *Id.* at 54,550. These “model vendors” would purchase model drugs from manufacturers at a negotiated price, and arrange for their distribution to providers and billing to Medicare. *Id.* Under that arrangement, “the model vendors, rather than the health care providers, would take on the financial risk of acquiring the drugs and billing Medicare.” *Id.*

92. Second, Medicare would pay model vendors for each model drug based on a formula indexed to the average price of the drug across 14 countries—Austria, Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Greece Ireland, Italy, Japan, Netherlands, and the United Kingdom. *Id.* at 54,557.

93. Third, Medicare would shift the calculation of the add-on payment to Part B providers from 6 percent of the prescribed drug’s ASP, to a “set payment amount per encounter or per month . . . for an administered drug, which would not vary based on the model payment for the drug itself.” *Id.* at 54,553.

94. The 2018 ANPRM proposed conducting a randomized test of the IPI Model across “geographic units.” *Id.* at 54,553. Under the proposed test, providers “in selected geographic areas” would be required to participate in the model. *Id.* at 54,552–53. Participants would be required to purchase model drugs from at least one model vendor. *Id.* at 54,552. “Outside of the designated model test areas and for drugs not included in the model, health care providers would continue” under Medicare’s ordinary payment policies. *Id.* at 54,550. The 2018 ANPRM advised that the geographic areas included in the model “would include 50 percent of Medicare Part B spending on separately payable Part B drugs.” *Id.* at 54,553.

95. The MFN Rule differs in numerous critical respects from the IPI Model discussed in the 2018 ANPRM. Among other things:

96. The 2018 ANPRM provided no indication that HHS was considering any test of a model in which Part B reimbursement rates would be based upon the *lowest* price prevailing in any one of numerous countries. Rather, the 2018 ANPRM proposed that Part B payments would be indexed to a drug’s *average* international price, multiplied by a CMS-selected factor to obtain an intermediate “Target Price” calibrated to achieve “about a 30 percent reduction in Medicare spending for included Part B drugs over time.” *Id.* at 54,556. Use of a “most favored nation”

1 approach raises numerous serious issues. For example, it creates the possibility that reimbursement
 2 rates will be set based on a single “outlier” country (where, for instance, a drug has no patent
 3 protection). As a result, President Trump estimated that the final MFN Rule would lead to a
 4 reduction of reimbursement rates as much as “80 percent” to “90 percent.”³¹ And implementing a
 5 “most favored nation” approach also requires the creation of a complex framework for determining
 6 which country actually has the “lowest” prices for a “drug.”

7 97. The 2018 ANPRM proposed “a randomized [test] design with the randomization to
 8 [model] and [control] groups occurring at the geographic unit of analysis.” *Id.* at 54,553. HHS
 9 specifically sought comment on the size of the geographic areas it should evaluate, and whether any
 10 geographic adjustments or exclusions would be appropriate. *Id.* at 54,554. It gave no indication, in
 11 other words, that a *nationwide* “test” was under consideration. Nor did it give any indication that it
 12 planned to conduct a test without randomization and comparison between model and control groups,
 13 and instead would use the no-control “interrupted time series” approach asserted in the MFN Rule.
 14 *See id.* at 54,553.

15 98. The MFN Rule does not include the “model vendors” that were integral to the 2018
 16 ANPRM. Without such vendors, manufacturers and healthcare providers have no intermediary in
 17 place to take on the financial risk between the acquisition price of the drug and the MFN
 18 reimbursement rate. This is particularly problematic given that most manufacturers do not sell drugs
 19 directly to healthcare providers, and consequently do not have visibility into whether a particular
 20 sale was made to a Medicare patient or to a patient with private insurance. The MFN Rule therefore
 21 requires healthcare providers to assume the financial risk that Medicare reimbursements to them for
 22 the drugs they use in their treatment of their patients will be far lower than the sales price the
 23 providers paid, which in turn will impact the healthcare providers’ financial ability to purchase the
 24 covered drugs. This risk poses a tremendous threat to patient’s access to the drugs. And it stands in
 25 stark contrast to the 2018 ANPRM, in which “the model vendors, rather than the health care
 26 providers, would take on the financial risk.” *Id.* at 54,550.

27 _____
 28 ³¹ Remarks by President Trump at Signing of Executive Orders on Lowering Drug Prices, The White House (July 24, 2020 from 3:45 PM ET to 4:28 PM ET), <https://tinyurl.com/yxa89x9k>.

1 99. Stakeholders were not afforded an opportunity to comment on these or any of the
2 other provisions of the MFN Rule before it became effective. HHS' failure to provide such an
3 opportunity plainly violates the requirements of the APA, but its violation is particularly significant
4 here, where HHS admits that there is no "reliable precedent in the U.S. market" for the MFN Rule,
5 and "an unusually high degree of uncertainty" about its potential impacts. 85 Fed. Reg. at 76,237.

6 100. In addition, in issuing the MFN Rule, HHS relied on two new studies estimating the
7 Rule's impact, but HHS again gave the Rule immediate effect before stakeholders could comment
8 on these studies. Among other flaws, one of the studies assumes that healthcare providers will accept
9 reduced revenue or find alternative, effective Part B treatments when that may not be possible; it
10 assumes that alternative products are available but acknowledges that additional burdens on patients
11 are likely to result and does not quantify the impacts; and it acknowledges that there may be negative
12 spillover effects in the non-Medicare market, but does not quantify this potential impact. *Id.* at
13 76,240–41, 76,243. HHS thus gave immediate effect to the MFN Rule without allowing stakeholders
14 to comment on the flaws in the studies HHS relied on in adopting that Rule.

15 101. Further, HHS acknowledges that, as a result of the MFN Rule, some healthcare
16 providers may suffer extreme financial hardship, *id.* at 76,222, and some Medicare patients may
17 receive inferior therapies with "lower efficacy or greater risks," or end up "postponing or forgoing
18 treatment" altogether. *Id.* at 76,244. This is directly contrary to the statutory requirements for any
19 test that CMMI is authorized to pursue under the statutory model provisions. *See* 42 U.S.C. § 1315a.
20 It also is contrary to HHS's obligation to protect patients' access to treatment. 42 U.S.C. § 18114.

21 102. And, as noted above, defendants rushed to put the MFN Rule in place before the start
22 of the next Administration without waiting for stakeholders to comment on the many potential
23 adverse impacts that the Rule could have on patients, health care providers, and manufacturers.

24 ***HHS Lacked The "Good Cause" Required by Statute to Make the MFN Rule Immediately***
25 ***Effective***

26 103. The MFN Rule states that there is "good cause" to dispense with the required notice
27 and comment. *See* 85 Fed. Reg. at 76,249–50. HHS asserts "that the increases in Part B premiums
28 and deductibles was largely due to rising spending on physician-administered drugs," that such price

1 increases could lead to “improper medication adherence or skipped treatment,” and that the
 2 economic disruptions caused by the COVID-19 pandemic, including supposedly “historic levels of
 3 unemployment,” “exacerbate[s]” these problems. *Id.* at 76,249. This rationale is baseless and thus
 4 does not satisfy the statutory good cause requirements. 5 U.S.C. § 553(b)(B); *see also* 42 U.S.C.
 5 § 1395hh(b)(2)(C).

6 104. First, the MFN Rule is plainly not a response to new emergency conditions. To the
 7 contrary, the Administration has long been pursuing action on drug pricing, and has been discussing
 8 its intention to alter the reimbursement formula for Medicare Part B drugs for over two years—
 9 before the pandemic even began. *See supra* at ¶¶ 26–43. Indeed, in the numerous statements the
 10 President and Administration made about its MFN policy from July 2020 until the MFN Rule was
 11 announced on November 20th, the COVID-19 pandemic was not mentioned, even though it had
 12 been raging for months. Furthermore, the MFN Rule includes no explanation as to why a proposed
 13 rule could not have been released during this period. If a proposed rule had been released in July,
 14 when the President first signed an Executive Order on the subject, there would have been time for
 15 notice-and-comment proceedings in the four months before the final rule was released in November.
 16 The agency’s delay in issuing a proposed rule does not provide a valid basis for dispensing with the
 17 APA’s notice and comment requirements.

18 105. Second, the MFN Rule expressly *excludes* all drugs authorized “to treat patients with
 19 suspected or confirmed COVID-19,” 42 C.F.R. § 513.130(b)(ix), on the ground that applying the
 20 “MFN Model” to COVID-19 drugs would impair the “rapid, widespread availability of such drugs in
 21 the U.S.” 85 Fed. Reg. at 76,191. Thus, the fact that adults 65 or older comprise 8 out of 10 U.S.
 22 deaths from COVID-19, *id.* at 76,249, does not explain why it is necessary to rush implementation of
 23 a rule that will alter reimbursement rates for Medicare Part B drugs that are *not* used to treat
 24 COVID-19.

25 106. Third, there is no basis for claiming that the MFN Rule must take immediate effect in
 26 order to address a sudden rise in spending on Part B medications. Instead, according to CMS’s own
 27 data, a comparison of the first quarter 2019 payment amount with the last quarter of 2018 reveals
 28 that, on average, there was no change in payment amounts for the top 50 Part B drugs, and more

1 recent quarter-to-quarter comparisons showed that, on average, payment amounts *decreased* from
 2 0.4 percent to 3.2 percent for the top 50 drugs. CMS, 2020 ASP Drug Pricing Files (last modified
 3 Nov. 13, 2020), <https://tinyurl.com/sp78dv6>; CMS, 2019 ASP Drug Pricing Files (last modified June
 4 1, 2020), <https://tinyurl.com/y4dz5zwu>.

5 107. Fourth, HHS asserts that immediate action is warranted because the pandemic has
 6 caused “historic levels of unemployment,” and “we are currently seeing a new surge in COVID-19
 7 cases *that may lead to additional hardship and requires immediate action.*” 85 Fed. Reg. at 76,249
 8 (emphasis added). But, as of November 2020, the “seasonally adjusted” civilian unemployment rate
 9 was 6.7%, which is not historically high. Civilian Unemployment Rate, Graphics for Economic
 10 News Releases, U.S. Bureau of Labor Statistics (last updated November 2020),
 11 <https://tinyurl.com/hnbvbp>. In fact, HHS acknowledges that there have been “positive economic
 12 and employment trends since the initial peak in April,” 85 Fed. Reg. at 76,249, and the
 13 Administration has stated that “our economy is rebounding far beyond any expectations.”³²
 14 Moreover, most Medicare beneficiaries are retirees and most have some type of supplemental
 15 insurance, meaning that they have secondary insurance that may cover the co-payments for Part B
 16 drugs. For instance, in 2016, 81% of Medicare beneficiaries had supplemental insurance either
 17 through employer-sponsored insurance (30%), Medigap (29%), or Medicaid (22%).³³ Thus, HHS
 18 has failed to identify a rational connection between economic dislocations caused by the COVID-19
 19 pandemic and the ability of Medicare beneficiaries to obtain their Part B medications under the ASP
 20 reimbursement methodology.

21 108. Fifth, HHS’s assertion that immediate implementation of the MFN Rule will alleviate
 22 economic hardships caused by COVID-19 is based on speculation. HHS claims that the MFN model
 23 “will provide *immediate relief* to Medicare beneficiaries through reduced copays for MFN drugs due
 24 to lower drug payments.” *Id.* at 76,249 (emphasis added). But this myopic focus on one impact of

25 ³² Remarks by President Trump During an Update on Operation Warp Speed, The White House
 26 (Nov. 13, 2020), <https://tinyurl.com/yylopdy3>. This purported rationale is also contrary to the
 27 Administration’s many statements that the COVID pandemic has *not* created an emergency
 situation. See Juana Summers, *Timeline: How Trump Has Downplayed The Coronavirus Pandemic*,
 National Public Radio (Oct. 2, 2020), <https://tinyurl.com/y32uoas7>.

28 ³³ Kaiser Family Foundation, *Sources of Supplemental Coverage Among Medicare Beneficiaries in 2016* (Nov. 28, 2018), <https://tinyurl.com/yde57hle>.

the rule ignores the rule’s many other adverse impacts. HHS assumes that reduced copays will ensure that the pandemic does not cause seniors to “stint[] on care,” *id.*, but it elsewhere admits that, in its first year of operation, the MFN Rule itself may cause nearly 10% of Medicare beneficiaries to have “no access” to their Medicare Part B drugs, *id.* at 76,237, that the savings HHS projects are “attributable to beneficiaries *not accessing their drugs through the Medicare benefit*,” *id.* (emphasis added), and that the “potential loss of access to certain drugs” may cause patients to incur “*additional medical expenses*” overall, *id.* at 76,247 (emphasis added). It also acknowledges that the MFN Rule is unprecedented and there is “an unusually high degree of uncertainty” about the potential impacts of its action. *Id.* at 76,237.

109. In short, HHS’s justification for giving the MFN Rule immediate effect is riddled with inconsistencies that make plain that it is an after-the-fact pretext.

Adverse Impact of the Most-Favored Nation Rule on Plaintiffs’ Members

110. The members of BIO, CLSA, and Biocom include leading biotechnology companies that are dedicated to pursuing groundbreaking science to discover and develop medicines for people with serious and life-threatening illnesses. As research-driven biotechnology companies, these members invest heavily in researching diseases and treatments. They rely on investment and revenue generated through the sale of existing medicines to finance research and development of innovative new medicines. For each successful new drug, there are many drugs that fail during the research and development process, and so the revenues generated from the successful drugs must cover not only the costs for developing that drug, but also the costs of developing products which fail in clinical trials.

111. Thus, biotechnology innovation relies on the availability of free market incentives and a fair reimbursement formula for innovators and investors as well as for providers and the patients they serve. These incentives have allowed pre-commercial, pre-revenue companies to weather the storm of uncertainty until they can bring a product to market. They have also incentivized companies to make larger investments into their research and development efforts, which, in turn, have allowed them to serve more patients, stimulate job growth and expand access to

1 life saving medicine.

2 112. If the MFN Rule is implemented, it will have substantial adverse effects on the
3 revenues of plaintiffs' members and other manufacturers of Part B drugs, revenues that they have
4 traditionally invested in research and development, jobs, and manufacturing to bring new medicines
5 to patients.

6 113. Plaintiffs' members generally do not sell Part B drugs directly to healthcare providers
7 (such as doctors and hospitals), but instead to distributors. Healthcare providers buy drugs from
8 those distributors, use them in their treatment of patients and—for drugs used for Medicare Part B
9 patients—seek reimbursement from Medicare. This is often referred to as the “buy and bill” model
10 for Part B drugs.

11 114. Healthcare providers generally cannot afford to buy and bill for Part B drugs at a loss,
12 so the price paid by a provider to the distributor for drugs used to treat Medicare beneficiaries cannot
13 generally exceed the reimbursement rate providers will receive from Medicare. In turn, the price
14 paid by a distributor to the manufacturer cannot exceed what healthcare providers are willing to pay
15 to the distributor.

16 115. Certain drugs are sold in foreign countries at lower prices than in the U.S. due to, a
17 host of reasons, including, among other things, price controls imposed by foreign governments,
18 weaker protections for intellectual property in those countries, differences in demand, or independent
19 decisions by third parties licensed to distribute those drugs overseas. Capping Medicare Part B
20 reimbursement rates at the lowest price paid for the drugs in other countries will therefore force
21 manufacturers such as plaintiffs' members either to reduce U.S. prices below the MFN Rule
22 reimbursement rates, and/or to lose market share as healthcare providers will stop prescribing their
23 drugs because the healthcare providers cannot pay more for the drugs than they will receive in
24 reimbursement from Medicare. Either course of action will impair the manufacturers' revenues and
25 related ability to develop new treatments.

26 116. Due to the role of distributors in the market, manufacturers and healthcare providers
27 cannot practically respond to the rule by using the MFN price for Medicare Part B sales, while also
28 maintaining the market rate for other sales, particularly given the Rule's immediate effective date.

1 Distributors do not differentiate the price they will pay to a manufacturer for a drug product based on
2 whether they will ultimately sell the drug to a healthcare provider for treatment of a Medicare patient
3 as opposed to treatment of a privately insured patient. By cutting the Medicare reimbursement rate,
4 the MFN Rule will therefore also change the commercial price that distributors are willing to pay
5 manufacturers for their products.

6 117. This problem is rendered particularly acute by the fact that the MFN Rule includes no
7 provision setting up vendors to acquire the price-controlled drugs for the Medicare program. *See*
8 ¶ 98, *supra*. That mechanism, which had been discussed in the International Pricing Index ANPRM
9 two years ago, would have mitigated to some degree the risk of unreimbursed costs that healthcare
10 providers face under the MFN Rule. The lack of a vendor mechanism—combined with the
11 immediate effective date of the Rule—will greatly increase harms to both manufacturers and
12 healthcare providers, as manufacturers will not have time to re-negotiate contracts or otherwise
13 stratify pricing, and as healthcare providers will bear the severe financial risk that Medicare
14 reimbursements will not match the prices they pay for the covered drugs. *Id.*

15 118. In addition, the MFN Rule will also likely impact the reimbursement rate paid for the
16 drugs by other programs, such as Medicaid and the 340B programs, as the reimbursement formulas
17 for those programs are determined based on, among other things, the average price paid to the
18 manufacturer by certain customers and the lowest price available to any entity for the drug.

19 119. Plaintiffs' members cannot avoid or substantially mitigate these adverse effects by
20 raising the prices at which they sell their products internationally or otherwise. In some countries,
21 drug prices are effectively set by the government or a government-backed healthcare provider. In
22 such countries, the government healthcare monopoly may be unwilling to pay an increased price. In
23 other countries, a drug may have no patent protection due to weaker intellectual property protections
24 in those countries, may have competitors on the market that are not approved in the U.S., or may be
25 sold in that geographic area by a different manufacturer entirely (which would have no incentive to
26 alter its pricing decisions simply to increase the price that would be paid to another manufacturer for
27 that drug in the United States).

28 120. Implementation of the MFN Rule will also hamper manufacturers' ability to meet

1 their statutory obligation to calculate and submit an ASP to CMS, for which there could be a risk of
2 significant penalties. 42 U.S.C. § 1396r–8(b)(3)(A)(iii). The Rule requires that manufacturers
3 exclude from the ASP calculation the units of drugs reimbursed according to the new MFN Rule.
4 But manufacturers—which, again, typically sell their drugs to wholesalers or distributors, which in
5 turn sell those drugs to healthcare providers to use in their treatment of their patients—generally
6 have no way to determine whether a drug purchased from them by a wholesaler or distributor will
7 ultimately be administered by a provider to treat a Medicare patient, rather than a patient with
8 Medicaid or commercial insurance. Indeed, even the wholesaler or distributor would not know when
9 its customer, such as a hospital outpatient department, administers a drug to a Medicare patient as
10 opposed to a Medicaid or a commercially insured patient, let alone how much the customer will be
11 reimbursed. For manufacturers to gain such downstream visibility into precisely who pays for their
12 drugs to treat which patients would require not only that manufacturers transform their price-
13 reporting systems, but also that wholesalers, distributors and others in the drug supply distribution
14 chain cooperate closely with manufacturers’ efforts in this regard—likely incurring considerable
15 expense in the process. Even if such a transformation were possible, it could not be effected for the
16 50 selected drugs in the MFN Rule in the scant five weeks provided before the Rule goes into effect.

17 121. The MFN Rule will also threaten the financial viability of some specialty practices by
18 reducing the reimbursement rate for the drugs subject to the MFN Rule to below the acquisition cost.
19 As discussed, Congress has fixed reimbursement rates at 6 (now at the sequestered 4.3) percent over
20 ASP. The MFN Rule would replace that percentage-based markup with a flat fee. 42 C.F.R.
21 § 513.220. The likely effect of the MFN Rule is that such providers will cease administering those
22 products which would be administered at a financial loss to the practice, which in turn will result in
23 lost revenue (as a result of the loss of patients whom the practice will no longer serve), and which
24 could result in some clinics being forced to close. In turn, such impacts on providers would both
25 make it more difficult or impossible for patients to obtain drugs subject to the MFN Rule and would
26 cost manufacturers revenues associated with the sale of drugs to those clinics. Thus, the MFN Rule,
27 particularly given its immediate effective date and lack of notice-and-comment process, will cause
28 unavoidable and irreparable harm to manufacturers, healthcare providers, and patients.

1 122. Finally, as plaintiffs explain next, implementation of the MFN Rule will also
2 significantly undermine the research and development efforts of their members.

3 ***The MFN Rule Will Severely Limit Drug Innovation and Patient Access***

4 123. The market-based system that Congress enacted for calculating Medicare
5 reimbursement rates for Part B and other Medicare-covered drugs ensures that more and newer
6 medicines are available sooner to Americans, with better health outcomes for those with serious
7 diseases. “Of the 74 cancer drugs launched between 2011 and 2018 worldwide, 95% are available in
8 the United States, whereas only 74% are available in the United Kingdom, 49% in Japan, and 8% in
9 Greece.” *Importing International Reference Pricing in the U.S. Jeopardizes Patient Access to*
10 *Innovative Medicines*, BIO, <https://www.bio.org/save-cures> (last accessed Dec. 4, 2020). Similarly,
11 “[n]early 90% of all new medicines launched since 2011 are available in the United States,
12 compared to 50% in France, 48% in Switzerland, and 46% in Canada.” *Id.* Many of the drugs
13 manufactured by BIO’s and CLSA’s and Biocom’s members are not available in many European
14 countries with price controls.

15 124. Price controls undermine the ability of companies to develop new medicines by
16 depriving them of funds necessary to do so. In the United States, investors receive a market-based
17 return on their investment, which is limited by the market value of the few products that ultimately
18 make it to market and are successful. Free markets spur investment in discovery, which, in turn,
19 benefits the public in the form of innovations that lead to trials and ultimately valuable new
20 treatments and cures for diseases. In a jurisdiction that employs price caps on prescription drugs, by
21 contrast, the potential return on investment is sharply limited.

22 125. These effects are well recognized. Indeed, in 2018, during a hearing before the Senate
23 Health Committee, HHS Secretary Azar testified that he did not believe a “most-favored-nation”
24 plan would be effective, because this type of plan could reduce the availability of drugs, as has
25 happened in other countries that set a “reference price.” Prescription Drug Pricing at 01:03:13, C-
26 SPAN (June 12, 2018), <https://tinyurl.com/y5a8yjsh>. The Administration itself opposed one bill that
27 aimed to cap prescription drug prices based on the average price in certain foreign countries, on the
28

ground that it would “compromise the health of Americans by dramatically reducing the incentive to bring innovative therapeutics to market.” Executive Office of the President, Statement of Administration Policy: *H.R. 3 – The Elijah E. Cummings Lower Drug Costs Now Act*, The White House (Dec. 10, 2019), <https://tinyurl.com/yye73sa9>; *see also* H.R. 3, 116th Cong. (2019), <https://tinyurl.com/y23bfxva>. Members of Congress have agreed that a “most-favored-nations” approach to drug pricing would not “be to the benefit of the adoption of and research for modern drugs.” Peter Sullivan, *Grassley Announces Opposition to Key Trump Proposal to Lower Drug Prices*, The Hill (June 19, 2019 at 3:19 PM ET), <https://tinyurl.com/yyozvjrh>.

126. The MFN Rule will deprive emerging biotechnology companies of their ability to attract crucial financing by seriously impacting their potential for market-based returns if the product is a success. As discussed above, the MFN Rule will cause pharmaceutical manufacturers to lose market share and/or to lower prices to avoid such losses. Either way, the MFN Rule reduces revenues, thereby limiting the return on investment in biopharmaceuticals. In an industry in which the success rate on research and development efforts is so low, the MFN Rule will impair the ability of companies to obtain financing. *Cf.* Ernst & Young, *Biotechnology Report 2017: Beyond Borders-Staying the Course* 18–19 (2017) (noting challenges in obtaining investment due to R&D costs and the need for the biotechnology industry to improve its return-on-investment), <https://tinyurl.com/y2ckrhcu>.

127. The biotechnology “industry relies heavily on private investments to fund research, and investors are clearly uncomfortable with the prospect of price controls, direct or indirect. Decreases in investor confidence can only result in a decrease in investment dollars, thereby placing critical research at risk. In addition, biopharmaceutical price controls will inevitably, and perhaps irreparably, damage the financial health of these dynamic companies and the hundreds of thousands of citizens they employ.” Letter from Alfred R. Berkeley III, President, NASDAQ, to Hon. Dennis J. Hastert, Speaker, U.S. House of Representatives (May 16, 2000) (on file with BIO); E&Y Biotechnology Report, *supra*, at 56 (“The November US election kept a lid on 2016 biotech financing, as capital became scarce amid discussion of drug price controls . . .”).

128. From 2000 to 2010, the U.S. was responsible for 57% of new medicine development

globally, whereas countries with price controls (France, Germany, Japan, and the United Kingdom), were responsible for only 29% of “new chemical entities developed[.]” Robert D. Atkinson, *Why Life-Sciences Innovation Is Politically ‘Purple’—and How Partisans Get It Wrong*, Info. Techn. & Innovation Found. (Feb. 2016), <https://tinyurl.com/yyup8nhg>. These pricing controls are why Europe no longer leads the world in biopharmaceutical R&D. Joseph H. Golec & John A. Vernon, *European Pharmaceutical Price Regulation, Firm Profitability, and R&D Spending* (NBER Working Paper 12676) (Aug. 2006) (“In 1986, EU pharmaceutical R&D exceeded U.S. R&D by about 24 percent, but by 2004, EU R&D trailed U.S. R&D by about 15 percent.”), <https://tinyurl.com/y6pnjml4>.

129. Economists have warned that, if foreign price controls had been adopted in the United States from 1986-2004, there would have been 117 fewer new medicines produced for worldwide use and 4,368 fewer research jobs in the United States. And a 2018 study by researchers with Precision Health Economics found that, if price controls had been eliminated in OECD countries, that would lead to a 9-12% increase in research by 2030 and the development of 13 more new drugs per year. Taylor T. Schwartz, MPH, et al., *The Impacts of Lifting Government Price Controls on Global Pharmaceutical Innovation and Population Health* (2018), <https://tinyurl.com/y24x97gz>.

130. A report published by the Brookings Institute estimated that, if European drug prices were increased by 20%, it “would result in substantially more drug discovery worldwide” and that, “such a European price increase would lead to \$10 trillion in welfare gains for Americans over the next 50 years.” Dana Goldman & Darius Lakdawalla, *The Global Burden of Medical Innovation*, Brookings (Jan. 30, 2018), <https://tinyurl.com/y9893bsn>.

131. The discrepancy in investment has resulted in a decrease in innovation. One study has indicated that, while EU consumers paid less for pharmaceuticals, these price controls resulted in “about \$5 billion in foregone R&D spending, 1680 fewer research jobs and 46 foregone new medicines.” Golec & Vernon, *supra*, at 6.

132. In the last thirty years, biotechnology research has yielded treatments for medical conditions including osteoporosis, heart attack, stroke, hemophilia, HIV/AIDS, chronic renal failure, multiple sclerosis, hepatitis, arthritis, anemia, pneumonia, infertility, attention deficit hyperactivity

1 disorder, migraine, diabetes, HPV, and multiple forms of cancer. The U.S. Chamber of Commerce
 2 described the biotechnology industry as the area with the greatest promise and potential. U.S. Dep't
 3 of Commerce, *A Survey of the Use of Biotechnology in U.S. Industry* vii (Nov. 2003),
 4 <https://tinyurl.com/y2bosxwn>.

5 133. However, this progress will stall without adequate investment into research and
 6 development. Currently, biotechnology “is one of the most research-intensive industries in the
 7 world.” *Biotechnology Industry Facts*, Bioprocess Online (Apr. 2, 2007),
 8 <https://tinyurl.com/y59cyldr>. For example, in 2016, “biopharmaceutical companies alone accounted
 9 for 52.3% of total [United States] R&D spending” Kelly Davio, *Report: US Medical Health*
 10 *Research Spending on the Rise, But for How Long?*, AJMC (Nov. 15, 2017),
 11 <https://tinyurl.com/yyug9c6e>.

12 134. The investment that a company makes to develop even a single therapy is enormous.
 13 The average cost of developing a therapy is approximately \$2.6 billion, and development takes 10-
 14 12 years. Policy & Medicine, *A Tough Road: Cost To Develop One New Drug Is \$2.6 Billion;*
 15 *Approval Rate for Drugs Entering Clinical Development is Less Than 12%* (Mar. 21, 2019),
 16 <https://tinyurl.com/s7bwq4a>. The chances that a biopharmaceutical will achieve FDA approval is
 17 “estimated to be less than 12%.” Biopharmaceutical Research & Development, The Process Behind
 18 New Medicines, PhRMA (2015), <https://tinyurl.com/yxn3er4y>. Of those therapies that do reach
 19 market, less than 10% of all U.S. biopharmaceutical companies make a profit selling brand name
 20 prescription drugs. *Importing International Reference Pricing in the U.S. Jeopardizes Patient Access*
 21 *to Innovative Medicines*, BIO, <https://www.bio.org/save-cures> (last accessed Dec. 4, 2020).

22 135. Importing foreign price controls into the U.S. market will have a particularly negative
 23 effect on the ability to develop new drugs to treat rare diseases and diseases for which drug
 24 discovery is especially difficult, including diseases such cancer and Alzheimer's, which have some
 25 of the lowest clinical trial success rates. The MFN Rule could make it no longer economically
 26 feasible to pursue approval for some new drugs, or to conduct research into whether existing drugs
 27 can be used to treat additional conditions. The Rule could therefore dramatically reshape clinical
 28 pipelines and future medicines available for patients with devastating conditions. Such changes will

1 be immediate and irreversible because research projects abandoned while awaiting resolution of this
 2 and other challenges to the MFN Rule may be restarted only years later, significantly slowing the
 3 entry of new drugs into the market.

4 136. The MFN Rule would hamstring the biotechnology industry as it currently exists,
 5 causing innovator firms to curb research and development efforts and reduce manufacturing
 6 capacity.

7 137. It is particularly ironic that HHS is invoking the COVID-19 pandemic as a basis for
 8 giving immediate effect to a Rule that will impair the current efforts of plaintiffs' members to
 9 respond to the COVID-19 pandemic. Plaintiffs' members are working to develop over 700 unique
 10 therapies to treat patients with COVID-19 related symptoms. *BIO COVID-19 Therapeutic*
 11 *Development Tracker*, BIO, <https://tinyurl.com/y948pgu4> (last updated Nov. 23, 2020 at 2:26 PM).
 12 Plaintiffs' members have also adjusted their manufacturing facilities to ensure that they can meet
 13 potentially increased demand for medicines that may be effective against COVID-19, at substantial
 14 cost and disruption. Even though COVID-19 drugs have themselves been excluded from the MFN
 15 Rule, by substantially reducing revenues from sales of their existing medicines, implementation of
 16 the MFN Rule would make it difficult, and potentially impossible, for Plaintiffs' members to
 17 maintain their current support for these COVID-19 related research and development initiatives,
 18 including potentially forcing them to cancel or postpone clinical trials for potential COVID-19
 19 treatments.

20 CLAIMS FOR RELIEF

21 FIRST CAUSE OF ACTION

22 *(Declaratory/Injunctive Relief – Defendants Issued the MFN Rule Without the Requisite*
 23 *Notice and Comment in Violation of the APA and the Medicare Act)*

24 138. The prior paragraphs of the Complaint are incorporated by reference.

25 139. The Administrative Procedure Act requires federal agencies to provide public notice
 26 of rule changes and an opportunity for comment, unless they “for good cause find[] . . . that notice
 27 and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.” 5
 28 U.S.C. § 553(b)(B); *see also* 42 U.S.C. § 1395hh (heightened notice-and-comment requirements for

1 regulations issued under the Medicare Act).

2 140. The APA also requires federal agencies to provide a minimum 30 days' notice before
 3 any substantive rule becomes effective, unless "otherwise provided by the agency for good cause
 4 found and published with the rule." 5 U.S.C. § 553(d)(3); *see also* 42 U.S.C. § 1395hh(e)(1)(B)(ii)
 5 (30-day period required for regulations under the Medicare Act unless the Secretary finds that
 6 waiver is "necessary to comply with statutory requirements" or where "application of such 30-day
 7 period is contrary to the public interest").

8 141. The MFN Rule was issued without prior public notice or an opportunity for comment,
 9 and without the statutorily required "good cause" to dispense with the notice-and-comment process.

10 142. The notice-and-comment requirements are an integral part of agency rulemaking, and
 11 particularly so where changes to payments under the Medicare Act are concerned. *See Azar v. Allina*
 12 *Health Servs.*, 139 S. Ct. 1804, 1809 (2019) ("Congress . . . decided that, with the growing scope of
 13 Medicare, notice and comment should become a matter not merely of administrative grace, but of
 14 statutory duty.").

15 143. Federal agencies may bypass the notice-and-comment requirements only "for good
 16 cause shown." 5 U.S.C. § 553(b)(B), (d)(3); *see also* 42 U.S.C. § 1395hh(b)(2)(C). Defendants have
 17 failed to satisfy this exception, which is "narrowly construed and only reluctantly countenanced."
 18 *California v. Azar*, 911 F.3d 558, 575 (9th Cir. 2018) (quoting *Alcaraz v. Block*, 746 F.2d 593, 612
 19 (9th Cir. 1984)), *cert. denied sub nom. Little Sisters of the Poor Jeanne Jugan Residence v.*
 20 *California*, 139 S. Ct. 2716 (2019).

21 144. The MFN Rule was issued on November 27, 2020, as an interim final rule with
 22 immediate effect.

23 145. HHS admits that it has not satisfied the notice-and-comment requirements of 5 U.S.C.
 24 § 553(b)(B) or (d)(3). HHS gave the MFN Rule immediate effect, and the Rule will begin to alter the
 25 Part B reimbursement rates on January 1, 2021, *before* stakeholders can comment on a wide range of
 26 important issues, including, among other things, deficiencies in the studies that HHS relied on in
 27 issuing the MFN Rule; serious implementation problems, including with respect to price reporting
 28 and reimbursement determinations; and the very significant adverse impacts the MFN Rule will have

on Medicare patients, Medicare providers, and the manufacturers of Medicare Part B drugs. *Supra* ¶¶ 99–103.

146. HHS’s assertion that there is “good cause” for dispensing with those requirements here lacks merit. 85 Fed. Reg. at 76,248–50. It contends that the pandemic requires immediate emergency measures. But, for the reasons explained above, the agency’s explanation is riddled with inconsistencies and invalid. *Supra* ¶¶ 103, 141–45. Indeed, this Court recently held that the economic impacts of the pandemic did not provide “good cause” to dispense with notice-and-comment proceedings for another rule, explaining that “the emergent nature of the COVID-19 pandemic writ large” could not justify such measures in the absence of an adequate showing “that the impact of the COVID-19 pandemic on domestic [economic conditions] justified dispensing with the ‘due deliberation’ that normally accompanies rulemaking to make changes to [an agency] program that even Defendants acknowledge are significant.” *Chamber of Commerce*, 2020 WL 7043877, at *1. This holding is equally applicable here.

147. For these reasons, the MFN Rule violates the requirements of the APA and the Medicare Act, and should be held unlawful and set aside.

SECOND CAUSE OF ACTION

(Declaratory/Injunctive Relief – The MFN Rule is Beyond the Secretary’s Testing Authority and Thus is in Excess of Statutory Authority and Ultra Vires)

148. The prior paragraphs of the Complaint are incorporated by reference.

149. Executive agencies and officers may act only pursuant to delegated authority. When an executive officer takes action outside of that authority, courts may intervene to declare the action to be in excess of statutory authority under the APA, *E. Bay Sanctuary Covenant v. Barr*, 964 F.3d 832, 845 (9th Cir. 2020) (“An agency action must be ‘set aside’ if it is ‘not in accordance with law,’ or ‘in excess of statutory jurisdiction, authority, or limitations.’ (citing 5 U.S.C. § 706(2)(A), (C))), or *ultra vires*, see *Sierra Club v. Trump*, 963 F.3d 874, 891 (9th Cir. 2020) (“[g]enerally, judicial relief is available to one who has been injured by an act of a government official which is in excess of his express or implied powers” (citation omitted)), *cert. granted*, No. 20-138, 2020 WL 6121565 (U.S. Oct. 19, 2020).

1 150. These mechanisms require courts to reestablish limits of executive branch authority
 2 and to protect the rights of injured parties through the courts' equitable jurisdiction. And courts
 3 presumptively have jurisdiction to review these claims, even when a statute includes a review-
 4 limiting provision such as 42 U.S.C. § 1315a(d)(2). *See Sierra Club*, 963 F.3d at 891 (“When an
 5 executive acts *ultra vires*, courts are normally available to reestablish the limits on his authority.”
 6 (quoting *Dart v. United States*, 848 F.2d 217, 224 (D.C. Cir. 1988)); *Aid Ass’n for Lutherans v. U.S.*
 7 *Postal Serv.*, 321 F.3d 1166, 1173 (D.C. Cir. 2003) (same).

8 151. HHS lacked authority to issue the MFN Rule under the provision allowing the
 9 Secretary “to test innovative payment and service delivery models to reduce program expenditures”
 10 while “preserving or enhancing the quality of care furnished to individuals.” 42 U.S.C.
 11 § 1315a(a)(1).

12 152. The MFN Rule is *ultra vires* and in excess of statutory authority because it is not a
 13 “test” of a “payment and service delivery model[]” that “addresses a defined population for which
 14 there are deficits in care.” 42 U.S.C. § 1315a. It is instead an effort to implement what the President
 15 has openly described as a “national policy” that is contrary to an express Act of Congress. It applies
 16 nationwide, governs reimbursement rates for nearly all providers, and resets by administrative fiat
 17 the price Medicare will pay for treatments that accounted for about three quarters of its Part B drug
 18 expenditures last year. The narrow testing provision does not give HHS authority to issue a sweeping
 19 rule that sets aside fundamental aspects of the Medicare statute on a nationwide basis to implement a
 20 national policy set forth in an Executive Order.

21 153. Under the statute, a “test” must involve a model that “addresses a defined
 22 population.” 42 U.S.C. § 1315a(b)(2)(A). The MFN Rule, however, applies to *all* patients covered
 23 by Medicare Part B as their primary payer, and who receive treatment from any but a tiny handful of
 24 excluded providers. 42 C.F.R. §§ 513.2 (defining “MFN Beneficiary”), 513.100(b)-(c) (defining
 25 providers as mandatory participants by default, subject to narrow exclusions).

26 154. Similarly, a “test” is supposed to be conducted in two phases, 42 U.S.C. § 1315a(b),
 27 (c), and the second phase is supposed to “expand . . . the duration and the scope of a model that is
 28 being tested under subsection (b).” *Id.* § 1315a(c). But here, the entire United States, all primary Part

1 B beneficiaries, nearly all Part B providers, and about three quarters of Part B’s drug spending are
2 already subject to the supposed “Phase I test.”

3 155. The statute authorizes the Secretary to waive the Medicare Act’s reimbursement
4 pricing provisions “solely for purposes of carrying out this section with respect to testing models
5 described in subsection (b) [Phase I],” *id.* § 1315a(d)(1), and directs the Secretary to submit
6 recommendations “for legislative action to facilitate the . . . expansion of successful payment
7 models.” *Id.* § 1315a(g). These provisions underscore the limited nature of a test. *A de facto*
8 nationwide alteration of Part B reimbursement prices cannot legitimately be achieved through use of
9 “waiver” authority to conduct a “test,” but instead is to be achieved through legislation that codifies
10 a successful model. Yet here, the MFN Rule effectively alters the Medicare reimbursement
11 formula—on a nationwide basis for seven full years—for the overwhelming majority (and a
12 potentially increasing percentage) of Medicare Part B drugs.

13 156. The President’s own statements further confirm that the MFN Rule is intended to
14 have a broader effect than the statute allows, and is thus in excess of the Secretary’s authority or
15 *ultra vires*. The President stated that his original (and unreleased) Executive Order on the MFN Rule
16 would “completely restructure the prescription drug market.”³⁴ The September 13, 2020 Executive
17 Order states that it is “the policy of the United States that the Medicare program should not pay more
18 for costly Part B or Part D prescription drugs or biological products than the most-favored nation
19 price.” Exec. Order No. 13,948, 85 Fed. Reg. 59,649, at § 2(a). The President has since stated that
20 “My Most Favored Nation order will ensure that *our Country* gets the same low price Big Pharma
21 gives to other countries.”³⁵ And, the President has proclaimed that his plan would reduce
22 prescription drug prices *generally*, and not for a limited population. For example, on July 30, 2020,
23 he stated that “Drug prices will soon be lowered massively.”³⁶ And on August 2, 2020, he stated:

24
25 ³⁴ Remarks, The White House, Remarks by President Trump at Signing of Executive Orders on
26 Lowering Drug Prices (July 24, 2020 from 3:45 PM ET to 4:28 PM ET),
<https://tinyurl.com/yxhpxvbs>.

27 ³⁵ @realDonaldTrump, TWITTER (Sept. 30, 2020, 2:58 PM), <https://tinyurl.com/yy4nea22> (emphasis
added).

28 ³⁶ @realDonaldTrump, TWITTER (July 30, 2020 at 9:44 AM), <https://tinyurl.com/y5y4b9ga>.

1 “YOU KNOW THAT DRUG PRICES ARE COMING DOWN, BIG. Favored Nations Clause
2 means USA will pay the lowest price of any nation in the World. Never done before. Watch!!!”³⁷

3 157. Because the MFN Rule will alter Part B reimbursements nationwide, it will
4 effectively repeal the statutory ASP provisions. *See* 42 U.S.C. § 1395w-3a(b)(1)(B), 1395w-3a(c).
5 The Secretary’s waiver authority extends only “as may be necessary *solely* for purposes of carrying
6 out this section *with respect to testing models described in subsection (b)[.]*” 42 U.S.C.
7 § 1315a(d)(1) (emphasis added) (relating to Phase I tests). Congress could not have intended this
8 limited testing provision to give the Secretary virtually untrammelled power to supersede the rest of
9 the carefully constructed statutory structure. *See, e.g., Whitman v. Am. Trucking Ass’n*s, 531 U.S.
10 457, 468 (2001) (“Congress, we have held, does not alter the fundamental details of a regulatory
11 scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in
12 mouseholes.”).

13 158. The statutory “Access to Therapy” provision further confirms that the MFN Rule
14 exceeds statutory authority and is *ultra vires*, because it will create “unreasonable barriers to the
15 ability of individuals to obtain appropriate medical care,” “impede[] timely access to health care
16 services” and “limit[] the availability of health care treatment for the full duration of a patient’s
17 medical needs,” by decreasing access to drugs and innovation into new therapies. 42 U.S.C. § 18114;
18 *see Planned Parenthood of Md. v. Azar*, 2020 WL 3893241, at *9 (D. Md. July, 20 2020), *appeal*
19 *docketed*, No. 20-2006 (4th Cir. Sept. 18, 2020). Indeed, HHS acknowledges that, as a result of the
20 MFN Rule, some Medicare patients “may experience access to care impacts,” including receiving
21 inferior therapies with “lower efficacy or greater risks,” or may even end up “postponing or forgoing
22 treatment” altogether. 85 Fed. Reg. at 76,244. It estimates that, during its first year, the MFN Rule
23 could cause nearly 10% of Medicare patients to lose access to their Medicare Part B drugs, and that
24 this percentage could increase to nearly 20% by its third year of operation. Furthermore, HHS
25 acknowledges that the “potential loss of access to certain drugs” may cause patients to incur
26 “additional medical expenses” overall. *Id.* at 76,247. The Rule exempts COVID-19 treatments on
27 this basis, but has no explanation why the same concerns do not apply to treatments for other

28 ³⁷ @realDonaldTrump, TWITTER (Aug. 2, 2020 at 8:01 AM), <https://tinyurl.com/y6qjt7h8>.

conditions as well. The Rule therefore violates the statutory requirements that HHS “shall not promulgate any regulation” that “impedes timely access to health care services,” “limits the availability of health care treatment,” or “creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care.” 42 U.S.C. § 18114.

159. For these reasons, the MFN Rule must be declared unlawful and enjoined because it exceeds HHS’s authority under the Medicare Act and is *ultra vires*.

THIRD CAUSE OF ACTION

(Declaratory/Injunctive Relief - Violation of the Non-Delegation Doctrine, Separation of Powers, and Presentment Clause)

160. The prior paragraphs of the Complaint are incorporated by reference.

161. The Constitution provides that “[a]ll legislative Powers herein granted shall be vested in a Congress of the United States.” U.S. Const., Art. I, § 1.

162. “From this language the Court has derived the non-delegation doctrine: that Congress may not constitutionally delegate its legislative power to another branch of Government.” *Touby v. United States*, 500 U.S. 160, 164–65 (1991). In exercising its legislative power, Congress may leave a certain amount of discretion to executive agencies and officials, but it must guide the exercise of that discretion with an “intelligible principle.” *Gundy v. United States*, 139 S. Ct. 2116, 2123 (2019).³⁸

163. Although cloaked as a “test,” the MFN Rule purports to discard Medicare’s statutory pricing nationwide, and adopt a drastically different pricing system, for nearly the entirety of Medicare Part B’s drug expenditures for the better part of a decade. *See* ¶¶ 80, 83, 154–55, *supra*.

164. If the MFN Rule is not *ultra vires* and instead reflects a legitimate use of the Secretary’s authority to “test” a “payment and service delivery model[]” that “addresses a defined population,” then the statute violates the non-delegation doctrine. As interpreted by the Secretary in promulgating the MFN Rule, none of the apparent limitations of the statute actually constrains the

³⁸ Concurring and dissenting Justices in *Gundy* expressed an interest in re-examining the non-delegation doctrine. *See Gundy*, 139 S.Ct. at 2130–31 (Alito, J., concurring in the judgment) (stating that “[i]f a majority of this Court were willing to reconsider the approach we have taken for the past 84 years, I would support that effort.”); 139 S.Ct. at 2141 (Gorsuch, J., dissenting) (criticizing the “intelligible principle” test).

Secretary’s discretion, and there is no “intelligible principle” to which the Secretary is directed to conform.

165. For similar reasons, if Section 1315a(d) is interpreted so broadly as to authorize the MFN Rule, it would violate the Presentment Clause and the constitutional principle of separation of powers. The executive branch cannot repeal provisions in a statute. *See Clinton v. City of New York*, 524 U.S. 417, 445 (1998) (“[W]hen enacting the statutes discussed in [*Marshall Field & Co. v. Clark*, 143 U.S. 649 (1892)], Congress itself made the decision to suspend or repeal the particular provisions at issue upon the occurrence of particular events subsequent to enactment, and it left only the determination of whether such events occurred up to the President.”); *Cnty. of Santa Clara v. Trump*, 250 F. Supp. 3d 497, 531 (N.D. Cal. 2017) (the President “cannot ‘repeal [] or amend[] parts of duly enacted statutes’ after they become law” (quoting *Clinton*, 524 U.S. at 439)).

166. If the MFN Rule is not *ultra vires*, it would give the Secretary essentially unlimited authority to repeal large portions of the Medicare statute, in violation of the Presentment Clause and the separation of powers.

167. Therefore, if the MFN Rule is authorized by statute, then Section 1315a(d) violates Article I, Section 1 of the U.S. Constitution and the Non-delegation Doctrine, and the Presentment Clause in Article I, Section 7.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request judgment against Defendants as follows:

- A declaration that the MFN Rule is procedurally invalid because it lacks the requisite notice and comment under the APA and the Medicare Act; that the MFN Rule is *ultra vires* and exceeds the Secretary’s Phase I testing authority; or that the statute’s waiver provision violates the non-delegation doctrine, the Presentment Clause, and the separation of powers, to the extent it permits the Secretary to exercise untrammelled nationwide waiver authority over the Medicare Act.
- A preliminary and permanent injunction prohibiting defendants from implementing or enforcing the MFN Rule, and vacating and setting the MFN Rule aside;
- Award of plaintiffs’ attorney fees and costs; and

- Such other relief as this Court may deem just and proper.

DATED: December 4, 2020

By: /s/ Naomi A. Igra

Naomi A. Igra (SBN 269095)
naomi.igra@sidley.com
SIDLEY AUSTIN LLP
555 California Street
Suite 2000
San Francisco, CA 94104
Telephone: +1 415 772 7495
Facsimile: +1 415 772 7400

Joseph R. Guerra (*pro hac vice* to be submitted)
jguerra@sidley.com
Erika L. Maley (*pro hac vice* to be submitted)
emaley@sidley.com
Sean C. Griffin (*pro hac vice* to be submitted)
sgriffin@sidley.com
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, D.C. 20005
Telephone: +1 202 736 8228
Facsimile: +1 202 736 8711

*Attorneys for Plaintiffs Biotechnology
Innovation Organization and Biocom
California*

Beth S. Brinkmann (SBN 129937)
bbrinkmann@cov.com
Mark Mosier (*pro hac vice* to be submitted)
mmosier@cov.com
Conrad Scott
cscott@cov.com
COVINGTON & BURLING LLP
One CityCenter
850 Tenth Street, N.W.
Washington, D.C. 20001
Telephone: +1 202 662 5312
Facsimile: +1 202 662 6291

*Attorneys for Plaintiff
California Life Sciences Association*